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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/029,408	12/26/2001	Larry Caldwell	CALD-005	3760
24353 7590 05/27/2010 BOZICEVIC, FIELD & FRANCIS LLP 1900 UNIVERSITY AVENUE SUITE 200 EAST PALO ALTO, CA 94303			EXAMINER VU, JAKE MINH	
			ART UNIT 1618	PAPER NUMBER
			MAIL DATE 05/27/2010	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/029,408	Applicant(s) CALDWELL ET AL.	
	Examiner JAKE M. VU	Art Unit 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 January 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,5-7,10,11,14-18,24-30 and 32-40 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,5-7,10,11,14-18,24-30 and 32-40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Receipt is acknowledged of Applicant's Request for Continued Examination and Amendment filed on 01/29/2010.

- Claims 1, 2, 6, 11, 24, 28, 33, 34 have been cancelled.
- Claims 3-4, 8-9, 12-13, 19-23, 31 have been cancelled.
- Claims 1-2, 5-7, 10-11, 14-18, 24-30, 32-40 are pending in the instant application.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114 was filed in this application after a decision by the Board of Patent Appeals and Interferences, but before the filing of a Notice of Appeal to the Court of Appeals for the Federal Circuit or the commencement of a civil action. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on 01/29/2010 has been entered.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claim 10 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 10 recites the limitation "said symptom" in claim 6. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-2, 5-7, 10-11, 14-18, 24-30, 32-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bockow (U.S. Patent No. 5,709,855) in view of Edwards (U.S. Patent No. 5,989,559), Herbert et al (Clinical Evaluation and Management of. Work-Related Carpal Tunnel Syndrome. American Jour of Industrial Med. 37:62-74 (2000)), Hirano *et al.* (U.S. Patent No. 5,869,087), Liebschutz (PCT Publication WO 02/22109 A2) and Applicant's Specification.

The Bockow patent teaches topical compositions for treating inflammation and/or pain (See Abstract), such as carpal tunnel syndrome (see col. 6, line 61). The compositions may contain a cyclooxygenase inhibitor such as diclofenac, indomethacin, ibuprofen and ketoprofen, in amounts ranging from 3% to 25% by weight (See Column

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5, Lines 23-43; and Column 6, Lines 40-42). The disclosed composition may be in various common forms of topical compositions such as gels and creams (See Column 6, Lines 4-15). The compositions are intended for application to warm-blooded animals including humans (See Column 3, Lines 6-15). The compositions may be applied from 1 to 4 times daily, and an occlusive bandage may be applied after the application of the composition for a period of 4 to 10 hours (See Column 7, Lines 15-24).

The Bockow patent does not explicitly disclose the treatment of carpal tunnel syndrome by applying a topical formulation to a palmar dermal surface proximal to the carpal tunnel, nor does it disclose the topical formulation in the form of a patch

The Edwards patent is used here as a teaching reference to show that it is commonly known in the prior art to apply topical medication on or near the loci of sites of pain, such as those caused by carpal tunnel syndrome (See Examples L, N, O, P, and Q).

The Herbert reference is used here as a teaching reference to show that it is commonly known in the prior art to use non-steroidal anti-inflammatory drugs (NSAID) to treat carpal tunnel syndrome (see Abstract and Introduction; pg. 65 at right column; pg. 70 at left column and Figure 1; pg. 71 under Anti-inflammatory Agents and Other Pharmacological Management) and to immobilizing the area of pain using a wrist splint (see pg. 65 at right column; pg. 70 at left column; and pg. 71 under Immobilization), which reads on a wrist band.

The Hirano *et al.* patent is used here to show that it is known in the art that non-steroidal anti-inflammatory drugs such as diclofenac, indomethacin, ibuprofen and

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ketoprofen may be formulated into a patch, to be included in amounts ranging from 0.1% to 10% by weight (See Column 1, Line 49-50; Column 3, Line 65 to Column 4, Line 19; and Claims 1 and 10).

The Liebschutz *et al.* reference discloses a patch containing NSAIDs, such as diclofenac (See Abstract; and pg. 1 at last paragraph). The diclofenac may be present in the form of diclofenac epolamine in an amount that is preferably from 1% to 5% of the matrix layer (See Page 3, Section (b)(1)),. Additional disclosures include: protective layer composed on polyester attached to the patch (see pg. 5, 5th paragraph), which would read on a polyester backing layering; adhesive matrix comprised of diclofenac (see pg. 2)

Applicant's specification disclosed that a patch consisting of a hydrogel adhesive spread on a polyester felt backing is a commercially available product (see specification at pg. 10, line 1-5).

It would be obvious to one of ordinary skill in the art at the time the instantly claimed invention was made to combine the disclosures of the prior art into the objects of the instantly claimed invention. As the Edwards patent demonstrates, the placement of topical medication on or near the loci of sites of pain, such as those caused by carpal tunnel syndrome, is commonly known by one of ordinary skill in the art, and is therefore obvious. As the Bockow and Edwards patents deal with the treatment of pain, the references are considered to be analogous. Thus, one of ordinary skill in the art has a reasonable expectation of success in applying the teachings of the Edwards patent to those of Bockow.

One of ordinary skill in the art would be motivated to combine the Bockow patent with the Hirano *et al.* patent in order to treat pain using a topical formulation in the form of a patch, for the reason that a patch may be considered less messy than the use of a cream or gel. As the Bockow and the Hirano *et al.* patents both deal with topical compositions containing commonly known anti-inflammatory substances, they are considered to be analogous, and therefore, one of ordinary skill in the art would have a reasonable expectation of success in combining the references together.

One of ordinary skill in the art would find it advantageous to use a patch containing an anti-inflammatory drug in conjunction with a wrist band. Bandages are well known for holding dressings and other topical formulations in place so as to avoid the loss of contact between the formulation between such a therapeutic composition and the affected area. Bandages are also useful in restricting the movement of a joint afflicted with pain so that the decrease in movement also decreases the chance of a sharp jerk or movement in the joint that may trigger additional pain as discussed in the Herbert reference above. In either application, a bandage applied to a subject suffering from carpal tunnel syndrome would constitute a "wrist strap" in the broad sense of the term, without any further or more specific definition by the instant disclosure. Thus, the instantly claimed invention is *prima facie* obvious.

It would be obvious to one of ordinary skill in the art to combine the Bockow patent with the Liebschutz *et al.* reference, as one would be motivated to use the patch disclosed in Liebschutz *et al.* for its disclosed several advantages, such as avoidance of stomach irritation and advantages of good adhesion without irritation and improved

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bioavailability (See Page 1 at last paragraph to page 2 at first paragraph). As the Bockow and Liebschutz *et al.* reference are both drawn to topical formulations of anti-inflammatory drugs such as diclofenac for the treatment of pain, the references are analogous and therefore, one of ordinary skill in the art would have a reasonable expectation of success in combining the references together. Thus, the instantly claimed invention is *prima facie* obvious.

It would have been obvious for one of ordinary skilled in the art to purchase and use a commercially available patch with polyester felt backing and hydrogel adhesive with the diclofenac, because it would have been easier than making from scratch.

The references do not specifically teach adding the ingredients in the amounts as claimed by Applicant. The amount of a specific ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ and reasonably would expect success. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient to add in order to best achieve the desired results, such as lowest amount of drug to dissipate the pain, or highest amount of drug before adverse effect, etc. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of ingredient amount would have been obvious at the time of Applicant's invention.

Response to Arguments

Applicant argues that neither Bockow nor Edwards teach or suggest a patch formulation. The Examiner finds argument unpersuasive, because as discussed above, Hirano and Lisebschutz teach using a patch and the motivations to use a patch, such as avoidance of stomach irritation and advantages of good adhesion without irritation and improved bioavailability (See Page 1 at last paragraph to page 2 at first paragraph).

Telephonic Inquiries

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JAKE M. VU whose telephone number is (571)272-8148. The examiner can normally be reached on Mon-Tue and Thu-Fri 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jake M. Vu/
Primary Examiner, Art Unit 1618